K093882

510(k) Summary
(*per 21 CFR 807.92*)
Sorin C5 System

JAN 15 2010

1. SPONSOR

Sorin Group Deutschland GmbH
Lindberghstrasse 25
80939 Munich
Germany
Contact Person: Renate Goebert
Telephone: 011 49 89 323 010

Date Prepared: December 1, 2009

2. DEVICE NAME

Proprietary Name:	Sorin C5 System
Common/Usual Name:	Heart lung machine console and integrated roller pumps
Classification Name:	Cardiopulmonary bypass console, (with integrated roller-type cardiopulmonary bypass pumps

3. PREDICATE DEVICES

Parent Device: Stöckert S5 System

4. DEVICE DESCRIPTION

The Sorin C5 System is a modification of the modular S5 System that comprises basic components and optional components. Optional components/accessories that have been cleared by the FDA for use as part of the S5 System are also compatible with the C5 System.

5. INTENDED USE/INDICATIONS FOR USE

The Sorin C5 System is indicated for speed-controlled pumping of blood through the cardiopulmonary bypass circuit for durations of six (6) hours or less, left ventricular venting, cardiotomy suction, and administration of cardioplegia solution, when used by a qualified perfusionist who is experienced in the operation of the System.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The Sorin C5 System is a modification of the Stöckert S5 System. The modified Stöckert S5 System is substantially equivalent to the parent Stöckert S5 System based on intended use, indication for use, operational characteristics, fundamental technological characteristics and performance specifications.

7. PERFORMANCE TESTING

Testing of the Sorin C5 System has demonstrated that the System fulfills prospectively defined performance criteria and that the modified System meets user needs.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Sorin Group Deutschland Gmbh
c/o Ms. Rosina Robinson
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, MA 02760

JAN 15 2010

Re: K093882
Trade/Device Name: Sorin C5 System, Model 58-00-00
Regulation Number: 21 CFR 870.4220
Regulation Name: Cardiopulmonary Bypass Heart Lung Machine Console
Regulatory Class: II
Product Code: DTQ
Dated: December 15, 2009
Received: December 18, 2009

Dear Ms. Robinson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K093882

Device Name: Sorin C5 System

Indications for Use:

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Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K093882